US ERA ARCHIVE DOCUMENT

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Case: 031340

MEMORANDUM

Subject:

EPA File Symbol/EPA Reg. No.: 432-TOA/Aqua Permanone, Submission of

Supplementary Information for Registration

From:

Carol E. Glasgow, Ph.D., Toxicologist Carol

Precautionary Review Section

Registration Support Branch (7505W)

Registration Division (7505C)

To:

George LaRocca, PM 13

Insecticide-Rodenticide Branch Registration Division (7505C)

Applicant:

AgrEvo Environmental Health

95 Chestnut Ridge Road Montvale, NJ 07645

FORMULATION FROM LABEL:

Active Ingredient (s):	% by weight
Permethrin	20.0
Piperonyl butoxide, technical	20.0
Inert ingredient(s)	60.0

BACKGROUND: AgrEvo submitted additional information on three studies (acute dermal toxicity, primary eye and dermal irritation) on Aqua Permanone as required in a November 16, 1995 Agency letter. Original studies performed by MB Research Laboratories, Inc. and reviewed by Mrs. Lucy Markarian of PRS on 8/9/95. She rated the acute oral toxicity Acceptable, the acute inhalation and the dermal sensitization as Unacceptable and three studies Supplementary for lack of the following information:

acute dermal toxicity: areas of application in measured units; the amount of test

material applied per cm²; thickness of gauze used for

covering the application site

primary eye irritation:

method of evaluation, i.e., source of light and/or if

magnification used

primary dermal irritation:

site and description of patch including thickness of patching material; confirmation of the size of application site; if the test material was applied to the skin directly; a description

of the semi-occlusive dressing.

On April 22, 1996, AgrEvo submitted MB Research Laboratories, Inc.'s response with the information Mrs. Markarian had said was missing.

RECOMMENDATION:

RSB/PRS findings are as follows:

The additional information is adequate to upgrade the tests from Supplementary to Acceptable.

TOXICITY PROFILES

Acute oral toxicity	III	Acceptable
Acute dermal toxicity	IV	Acceptable
Acute inhalation toxicity		Unacceptable
Primary eye irritation	IV	Acceptable
Primary dermal irritation	IV	Acceptable
Dermal sensitization		Unacceptable

<u>LABELING</u>: No labeling language will be provided until acceptable acute inhalation and dermal sensitization studies are submitted.

